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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/878,641	06/11/2001	Cato T. Laurencin	DRE-0055	2890
26259	7590	10/05/2004	EXAMINER	
LICATLA & TYRRELL P.C. 66 E. MAIN STREET MARLTON, NJ 08053			CHATTOPADHYAY, URMI	
			ART UNIT	PAPER NUMBER
			3738	
DATE MAILED: 10/05/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/878,641

Applicant(s)

LAURENCIN ET AL.

Examiner

Urmi Chattopadhyay

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 September 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Request for Continued Examination

1. The request filed on 9/27/04 for a Request for Continued Examination (RCE) under 37 CFR 1.114 based on Application No. 09/878,641 is acceptable and a RCE has been established. An action on the RCE follows.

Response to Amendment

2. The amendment filed 6/28/04 has been entered. The changes to claims 1 and 2 have been approved by the examiner.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1-3 and 6-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wolowacz et al. (WO 95/01810 A1, as cited in applicant's IDS) in view of Chervitz (USPN 4,917,699 as cited in previous office action).

Wolowacz et al. discloses a replacement construct for tendons or ligaments with all the elements of claims 1 and 2, but is silent to the braided scaffold being a three-dimensional braided scaffold formed using a three-dimensional textile braiding technique. The ligament replacement

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(page 1, lines 3-5) includes a braided polymeric fiber-based (page 16, lines 32-35), degradable scaffold (page 2, lines 5-11). The scaffold is seeded with cells (page 1, lines 27-30) using a method that implies that the scaffold is porous (page 17, lines 19-21). See page 8, lines 20-21 for the ingrowth of the cells being supported by the scaffold. Chervitz teaches a prosthetic ligament comprising a three-dimensional braided scaffold formed using a three-dimensional textile braiding technique in order for an individual strand of fiber to extend in all directions within the prosthetic ligament to generate strength and elasticity akin to that for natural ligaments. The three-dimensional braiding also provides the optimal orientation for a plurality of fibers to substantially replicate the behavior of natural ligament and the increased fiber redundancy to reduce cracks. See column 2, lines 43-49 and column 3, lines 1-27. It would have been obvious to one of ordinary skill in the art at the time of applicant's invention to look to the teachings of Chervitz to modify the standard braided scaffold of Wolowacz et al. to a three-dimensional braided scaffold formed using a three-dimensional textile braiding technique in order for the prosthetic ligament to generate strength and elasticity akin to that for natural ligaments. The three-dimensional braiding also provides the optimal orientation for a plurality of fibers to substantially replicate the behavior of natural ligament and the increased fiber redundancy to reduce cracks. See column 1, lines 26-32 and 43-50.

Claim 3, see page 2, lines 1-3 for the cells being fibroblasts, which are mesenchymal in origin.

Claims 6 and 7, see page 1, lines 3-5 and page 5, lines 4-16 for a method of replacing a damaged ligament.

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Claim 8, see pages 16-17, steps (a)-(c) of Example 1 for a method of producing a graft material composed of living cells in a degradable matrix comprising harvesting and culturing cells in a culture and seeding the cultured cells onto the scaffold of claim 1 by sucking cell suspension through the scaffold under vacuum.

Claim 9, see page 16, lines 18-20 for the cells being fibroblasts, which are mesenchymal in origin.

5. Claims 4, 5, 10 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wolowacz et al. in view of Chervitz as applied to claims 2 and 8 above, and further in view of Vacanti (USPN 5,855,610 as cited in previous office action).

Wolowacz et al., as modified by Chervitz, discloses a replacement construct for tendons or ligaments and a method of producing a graft material with all the elements of claims 2 and 8, including the cells being precursor cells to fibroblasts (page 2, lines 1-3), but is silent to the cells generating mesenchymal cells, as required by claims 4 and 10, and of the cells being pluripotent stem cells, as required by claims 5 and 11. Vacanti et al. teaches a replacement construct comprising a degradable, polymeric fiber-based, porous scaffold seeded with cells, wherein the cells are pluripotent stem cells because they are immunologically inert. See column 6, lines 50-53. It would have been obvious to one of ordinary skill in the art to modify the replacement construct of Wolowacz et al. by seeding the scaffold with pluripotent stem cells, which are cells that generate mesenchymal cells, because they are immunologically inert.

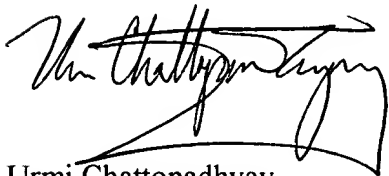
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Response to Arguments

6. Applicant's arguments with respect to claims 1-11 have been considered but are moot in view of the new ground(s) of rejection.

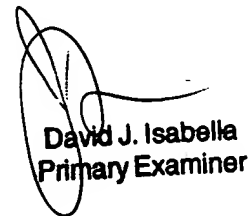
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ms. Urmi Chattopadhyay whose telephone number is (703) 308-8510 and whose work schedule is Monday-Friday, 9:00am – 6:30pm with every other Friday off. The examiner's supervisor, Corrine McDermott, may be reached at (703) 308-2111. The group receptionist may be reached at (703) 308-0858.

Should the applicant wish to send a fax for official entry into the file wrapper the Group fax number is (703) 872-9306. Should applicant wish to send a fax for discussion purposes only, the art unit fax number is (703) 308-2708.



Urmi Chattopadhyay

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David J. Isabella
Primary Examiner